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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,772	12/03/2001	Joaquina Faour	PHUS-7	7970

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INNOVAR, LLC  
P O BOX 250647  
PLANO, TX 75025

EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/004,772

Applicant(s)

FAOUR ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Reissue Applications***

Receipt of supplemental preliminary amendment dated 3-28-02 and Information Disclosure Statement, dated 4-24-02 is acknowledged.

***Oath/Declaration***

1. The reissue oath/declaration filed with this application is defective because it fails to identify the country of priority claim document. For any additional error corrected, which is not covered by the original oath or declaration, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant. SEE MPEP 1415.

2. Newly added claims do not comply with 37 CFR 1.173(b). The newly added claims should be underlined. See MPEP 1453 for manner of making amendments.

***Summary of Invention***

Instant claims 1-23 are directed to an improved multi-layered osmotic device comprising a core containing an active agent, a semi permeable membrane surrounding the core, an inert completely erodible or water soluble polymer coat comprising polyvinylpyrrolidone-vinyl acetate (PVP-VA) and an external coat comprising a second active agent. Claims 24-26 recite a multi-layered osmotic device similar to claim 1, without the specific polymer PVP-VA of claim 1. Instead claim 24 recites an inert, completely erodible or water-soluble polymer. Claim 25 recites external coat is for immediate release. Claim 27 is similar to claim 24, except that the

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claim recites different relebase rates of active agent from the external coat. Dependent claims 28-35 recite various relebase rates or different active agents. Claim 36 recites a specific polymeric coat, PVP-VA. Claims 37-39 recite additional ingredients in polymer coat. Claims 40-49 recite active agents.

***Claim Rejections - 35 USC § 112***

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim recites an "an improved multi-layered osmotic device" but does not state what is the improvement over the known osmotic devices. Accordingly, it is unclear whether the recited parts of the device are an improvement or not.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-35 and 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,681,584 to Savastano et al (Savastano) US 5,609,590 to Herbig et al (hereafter Herbig).

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Savastano teaches a controlled release drug delivery device to administer drugs either intermittently or to a pre-selected region of the gastro-intestinal region. The device comprises a core containing a drug and a binder such as polyvinylpyrrolidone (PVP) (cols. 7 and 8); a semi permeable membrane with a release orifice comprising cellulose acetate, polyethylene glycol (PEG) etc., (cols. 9 and 10); an enteric coating to prevent the dissolution of the delay jacket and the core comprising PEG, hydroxypropylmethylcellulose (HPMC), polyvinyl acetate phthalate, copolymers of methacrylic acid etc., (col. 11 and example 1 on columns 12 and 13); and finally an optional coating over the enteric coat containing a second drug for initial burst or immediate release (col. 12) comprising PVP and PEG (see example 4). The enteric coat of Savastano helps to keep the drug intact even in the presence of acidic gastric juices and enables a controlled release of the active drug in the gastrointestinal tract. Savastano teaches virtually any active agent in their device. Savastano suggests including an orifice or an opening in the core, depending on the solubility of the active agent (col. 9, lines 45-58).

Savastano fails to teach an inert, completely erodible or water-soluble polymer coat over the semi permeable membrane.

Herbig teaches a pH-triggered osmotic device for dispensing beneficial agent to an aqueous environment, comprising a beneficial agent and osmagent (which together reads on the instant core), surrounded by a semi permeable membrane. The polymers that are suitable for forming the semi permeable membrane are described in col. 4-5. A trigger means is used that is capable of losing its physical strength following triggering by a solution of the desired pH (col. 6, lines 40-44). Further, Herbig teaches that the pH-sensitive trigger means is attached to the semi permeable membrane or coated over the semi permeable membrane (col. 6, lines 59-65).

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Herbig teaches polymers that are suitable as the pH-sensitive trigger means, including polymers such as cellulose acetate phthalate, polyacrylamides, polyvinyl acetate phthalate etc (col. 7, lines 10-40), all of which are also described in the instant specification as suitable materials for the polymeric coat c), claimed. Thus, the pH-sensitive trigger material of Herbig reads on the instant polymer coat c). Herbig also suggests blending the pH-sensitive trigger materials with an inert non-dissolving polymer, so as to lengthen the time lag after triggering and subsequent to release of the beneficial agent (col. 7, lines 40-60). Herbig teaches several beneficial agents that could be delivered using their device (col. 9, lines 16-53) and other conventional excipients that includes the claimed polyethylene glycol.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include the pH-sensitive trigger polymers of Herbig (which reads on the instant polymer coat), as a coating or a partial encasing over the semi permeable membrane of Savastano because both Savastano and Herbig teach osmotic drug delivery devices to releas drug to a desired region and Herbig suggests that combining osmotic delivery systems with pH-sensitive trigger systems enables one to control the time lag prior to delivery of the beneficial agent. Accordingly, one of an ordinary skill in the art would have expected to have a better control over the time of release of a beneficial agent in the osmotic delivery device of Savastano by adding a pH-sensitive polymer layer or coat of Herbig.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
January 9, 2003



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600